

REMARKS

I. Status of the Application

Claims 46-55, 61-76, 85, 86 and 90-92 are presently pending in the instant application.

Claims 46-55, 62-71, 73-76, 85, 86 and 90-92 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Simone, U.S. Patent No. 5,397,786, in view of Thomas et al., U.S. Patent No. 5,972,985, Buchholz et al., U.S. Patent No. 6,514,973, and Hageman et al., U.S. Patent No. 6,420,342. Claim 72 remains rejected under 35 U.S.C. § 103(a) as being unpatentable over Simone in view of Thomas et al., Buchholz et al., and Kampinga et al., U.S. Patent No. 6,455,511, and further in view of Kuznicki et al., U.S. Patent No. 5,464,619. Applicants respectfully request entry and consideration of the foregoing comments, which are intended to place the case in condition for allowance.

II. Claims 46-55, 62-71, 73-76, 85, 86 and 90-92 Are Nonobvious over Simone, Thomas et al., Buchholz et al. and Hageman et al.

At page 3, section 7 of the Final Office Action, claims 46-55, 62-71, 73-76, 85, 86 and 90-92 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Simone, U.S. Patent No. 5,397,786, in view of Thomas et al., U.S. Patent No. 5,972,985, Buchholz et al., U.S. Patent No. 6,514,973, and Hageman et al., U.S. Patent No. 6,420,342. Applicants respectfully traverse this rejection. The combination of cited references fails to teach or suggest Applicants' claimed invention.

The claimed invention is based in part on Applicants' surprising discovery that a beverage containing the claimed unique combination of digestible carbohydrate in the amount of between 20 – 75 g/l, a hypotonic osmolarity in the range of 70 to 275 mOsm/l and at least one methyl amine selected from dimethylglycine and sarcosine can successfully treat hypohydration. Applicants'

claimed fluids differ from typical beverages known in the art for treating dehydration as these art-known beverages are characteristically hypertonic and often contain high concentrations of compounds that are a fast energy source (paragraph [0017] of the published application) such as sugar, which can be undesirable for dietary and digestive reasons. The beverage formulations for beverages known in the art at the time of filing fail to adequately address a variety of parameters that are critical to consider when treating hypohydration, such as the rate of gastric emptying, the protection of tissues and organs against detrimental effects on their functioning, and the alteration of levels of endogenous compounds such as blood mineral, amine and glucose levels (paragraph [0017] of the published application).

In contrast to these art-known beverages, Applicants have surprisingly discovered that a fluid having a digestible carbohydrate amount of 20-75 g/l has been found to be very effective for treating hypohydration, and that the water uptake after ingestion of such a fluid has been established to be very rapid (paragraph [0032] of the published application). Further, Applicants have determined that the claimed digestible carbohydrate promotes the absorption of water by the body. *Id.* Applicants have also discovered that the claimed osmotic pressure has a beneficial effect on the speed of water uptake by the body (paragraph [0031] of the published application). Accordingly, Applicants' claimed fluid for treating hypohydration contributes to the prevention of bodily water perturbations, promotes homeostasis, and rapidly restores the water content of the body after dehydration (paragraph [0018] of the published application). Further, the claimed fluid is effective in protecting against the secondary effects of hypohydration without giving rise to undesired side effects. *Id.*

Simone fails to teach or suggest the claimed invention. The Office Action asserts that Simone teaches a ***hypotonic*** rehydration or nutritional drink (page 3). Nowhere does Simone expressly teach or suggest the desirability of ***any*** hypotonic beverage, let alone a hypotonic beverage

having the claimed osmolarity. Nowhere does Simone teach or suggest the criticality of a hypotonic beverage for treating hypohydration and, based on the teachings of Simone, one of skill in the art would have no reason to believe that this would be so. Instead, Simone teaches a variety of beverage compositions that would be considered *hypertonic* (See Simone, Table 1; also paragraph [0013] of Applicants' published specification). In fact, Simone teaches that “[t]he *preferred* liquid composition of the present invention combines about *30 different macronutrients and micronutrients*. Very surprisingly, a *truly spectacular result* is obtained, eliminating nearly completely all fatigue and dehydration symptoms, in both the sports and with dehydrated patients” (column 5, lines 26-31, emphasis added). Simone provides two working examples of specific formulations, each of which contain 31 macronutrients and micronutrients (See Table 1). These compositions would not be considered hypotonic (paragraph [0013] of Applicants' published specification).

Based on the teachings of Simone, one of skill in the art would find no motivation or guidance to make a hypotonic fluid that treats hypohydration. Further, for at least the reasons set forth in Applicants' Amendment and Response filed December 18, 2006, Simone fails to teach or suggest a fluid containing dimethylglycine or sarcosine, a fluid having a specific hypotonic osmolarity in the range of 70 to 275 mOsm/l, or a hypotonic solution that treats hypohydration when administered to a subject, as claimed by Applicants. Accordingly, Simone fails to render the claimed invention obvious.

Thomas et al. fails to cure the deficiencies of Simone. Thomas et al. is directed to nutriceutical compositions useful as dietary supplements (abstract). Thomas fails to teach or suggest a hypotonic fluid that treats hypohydration when administered to a subject, the claimed osmolarity of between 70 and 275 mOsm/l, or a methyl amine elected from dimethylglycine and sarcosine, as

claimed by Applicants. Accordingly, the combination of Simone and Thomas et al. fails to render the claimed invention obvious.

Buchholz et al. fails to cure the deficiencies of Simone and Thomas et al. Buchholz et al. is directed to compositions for the treatment and prevention of transmethylation disorders such as neurological and pathopsychological diseases (column 1, lines 7-9). Buchholz et al. fails to teach or suggest a hypotonic fluid that treats hypohydration when administered to a subject or an osmolarity of between 70 and 275 mOsm/l, as claimed by Applicants. Furthermore, nowhere does Buchholz et al. teach or suggest that dimethylglycine or sarcosine can be used in a fluid that treats hypohydration when administered to a subject, and one of skill in the art, based on the teachings of Buchholz et al. would have no reason to believe that this would be so.

As discussed in Applicants' response filed December 18, 2006, Buchholz et al. is directed to compositions for the treatment and prevention of transmethylation disorders such as neurological and pathophysiological diseases (column 1, lines 4-9), *not* for the treatment of hypohydration. Although sarcosine, dimethylglycine and betaine are all methyl donors used for transmethylation, it is not the role of methyl donor that renders sarcosine and dimethylglycine particularly suitable for use in the present invention. Instead, it is their ability to act as osmolytes that renders them useful in a fluid that treats hypohydration. Although Buchholz teaches the use of methyl amines, it is for their use as methyl donors for transmethylation. Further, sarcosine and dimethylglycine have physical characteristics that differ greatly from those of betaine. In particular, due to differing solubility profiles, differing amine structures and differing metabolic profiles, one of skill in the art would not conclude that sarcosine or dimethylglycine could readily be substituted for betaine in a fluid that treats hypohydration. Accordingly, one of skill in the art would find no motivation to replace betaine with sarcosine or dimethylglycine to arrive at the claimed invention.

For at least these reasons, the combination of Simone, Thomas et al. and Buchholz et al. fails to render the claimed invention obvious.

Hageman et al. fails to cure the deficiencies of Simone, Thomas et al. and Buchholz et al. Hageman et al. is directed to nutritional, pharmaceutical or dietetic preparations that comprise ribose or folic acid or functional analogs thereof in the prevention and treatment of diseases related to nucleotide metabolism disorders or insufficiencies (column 1, lines 5-10). Hageman et al. fails to teach or suggest a hypotonic fluid that treats hypohydration when administered to a subject, an osmolarity of between 70 and 275 mOsm/l or a methyl amine elected from dimethylglycine and sarcosine, as claimed by Applicants. Accordingly, the combination of Simone, Thomas et al., Buchholz et al. and Hageman et al. fails to render the claimed invention obvious.

Thus, the cited references, alone or in combination, fail to render the claimed invention obvious. Accordingly, Applicants respectfully request that the rejection of claims 46-55, 62-71, 73-76, 85, 86 and 90-92 under 35 U.S.C. § 103(a) as being unpatentable over Simone, in view of Thomas et al., Buchholz et al. and Hageman et al., be reconsidered and withdrawn.

III. Claim 72 Is Nonobvious over Simone in View of Thomas et al., Buchholz et al. and Kampinga et al., further in View of Kuznicki et al.

At page 7, section 5 of the instant Office Action, claim 72 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Simone in view of Thomas et al., Buchholz et al. and Kampinga et al., U.S. Patent No. 6,455,511, and further in view of Kuznicki et al., U.S. Patent No. 5,464,619. The Office Action states that the cited references in combination make clear that the use of caffeine in rehydration solutions is old and well known, and that the combination of references makes clear that the formulation containing diemthylglycine, one or more digestible carbohydrates (e.g., glucose, fructose, galactose, mannose, ribose and inositol), minerals, caffeine, glycerol and vitamins are old

and well known. The Office Action is silent as to why Kampinga et al., in combination with the other cited references, would render the claimed invention obvious. Applicants respectfully traverse this rejection.

The combination of cited references fails to render claim 72 obvious. Simone, Thomas et al. and Buchholz et al. fail to teach or suggest claim 72 for at least the reasons set forth above.

Kampinga et al. fails to cure the deficiencies of Simone, Thomas et al. and Buchholz et al. Kampinga et al. is directed to sports beverage compositions containing trehalose (column 1, lines 11-13). Trehalose is a *non-digestible* sugar substitute that is fermented by intestinal bacteria (See Attachment A, abstract; page 1260, first full paragraph; Table 5). In contrast to trehalose, Applicants' claimed invention is directed in part to a fluid for treating hypohydration comprising a *digestible* carbohydrate in the amount of between 20-75 g/l.

Although Kampinga et al. teaches that other carbohydrates or salts may be added to their formulations, they would only be added in small amounts to supplement added trehalose to achieve an osmolarity of *only 30 mOsm*: “if the concentration of trehalose is insufficient to attain 30 mOsm, additional carbohydrates or salts may be added to increase the osmolarity” (column 4, lines 25-28). Nowhere does Kampinga et al. teach or suggest a fluid for treating hypohydration comprising a digestible carbohydrate in the amount of between 20-75 g/l, as claimed by Applicants. Indeed, Kampinga et al. teaches, “sports beverage formulations containing *trehalose* as the *major carbohydrate source*,” (column 2, lines 18-19, emphasis added). Accordingly, trehalose is the desired carbohydrate in the compositions of Kampinga et al. and only very small amounts of digestible carbohydrates, if any, would be added to the compositions of Kampinga et al. Thus, one of skill in the art would find no motivation in Kampinga et al. to arrive at the claimed invention.

Finally, as discussed in Applicants' prior response, Kampinga et al. fails to teach or suggest a fluid that treats hypohydration including sarcosine or dimethylglycine, as claimed by Applicants.

Kuznicki et al. fails to cure the deficiencies of Simone, Thomas et al., Buchholz et al. and Kampinga et al. Kuznicki et al. is directed to beverages in which cellular hydration and drinkability are enhanced by the inclusion of green tea solids (column 1, lines 10-14). Kuznicki et al. fails to teach a hypotonic fluid comprising a digestible carbohydrate in the amount of between 20-75 g/l, let alone a fluid having an osmolarity of between 70 and 275 mOsm/l or a containing a methyl amine elected from dimethylglycine and sarcosine, as claimed by Applicants. Accordingly, the combination of Simone, Thomas et al., Buchholz et al., Kampinga et al. and Kuznicki et al. fails to render the claimed invention obvious.

Thus, the cited references, alone or in combination, fail to render claim 72 obvious. Thus, Applicants respectfully request that this rejection be reconsidered and withdrawn.

IV. Conclusion

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants' attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 720-9600. The Commissioner is hereby authorized to charge any additional fees or credit overpayment to Deposit Account No. 19-0733.

Respectfully submitted,

Dated: March 16, 2007



Judith L. Stone-Hulslander, Reg. No. 55,652
BANNER & WITCOFF, LTD.
28 State Street, 28th Floor
Boston, MA 02109
(617) 720-9600